

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

In RE: BOSTON SCIENTIFIC CORPORATION
PELVIC REPAIR SYSTEMS PRODUCTS
LIABILITY LITIGATION

MDL No.: 2326

THIS DOCUMENT RELATES TO:

Kimberly Allen v. Boston Scientific Corporation, 2:17-cv-01837
Perla Alvarado v. Boston Scientific Corporation, 2:17-cv-02243
Christine Babcock v. Boston Scientific Corporation, 2:17-cv-00701
Charise Beach v. Boston Scientific Corporation, 2:17-cv-2112
Michelle Briggs v. Boston Scientific Corporation, 2:17-cv-01844
Tracy Brown v. Boston Scientific Corporation, 2:17-cv-01243
Amy Busby v. Boston Scientific Corporation, 2:17-cv-2111
Sandra Clark v. Boston Scientific Corporation, 2:17-cv-02110
Jaime Conley v. Boston Scientific Corporation, 2:17-cv-01940
Linda Dembski v. Boston Scientific Corporation, 2:17-cv-01074
Bonnie Evans v. Boston Scientific Corporation, 2:17-cv-01242
Amy Harrison-Hood v. Boston Scientific Corporation, 2:17-cv-02641
Anita Hauff v. Boston Scientific Corporation, 2:17-cv-01900
Tracy Lowrie v. Boston Scientific Corporation, 2:17-cv-01959
Dana Mahnke v. Boston Scientific Corporation, 2:17-cv-00568
Mary Masterson v. Boston Scientific Corporation, 2:17-cv-02417
Rhea Notestine v. Boston Scientific Corporation, 2:17-cv-00534
Donna Palmer v. Boston Scientific Corporation, 2:17-cv-02416
Sherry Pierson v. Boston Scientific Corporation, 2:17-cv-02633
Armentha Price v. Boston Scientific Corporation, 2:17-cv-01939
Debora Ross v. Boston Scientific Corporation, 2:17-cv-02107
Annette Schroder v. Boston Scientific Corporation, 2:17-cv-01938
Brenda Shiflet v. Boston Scientific Corporation, 2:17-cv-01845
Donita Snow v. Boston Scientific Corporation, 2:17-cv-00704
Pamela Solomon v. Boston Scientific Corporation, 2:17-cv-02551
Margaret Speed v. Boston Scientific Corporation, 2:17-cv-02244
Bonnie Stapf v. Boston Scientific Corporation, 2:17-cv-02787
Stella Sustaita v. Boston Scientific Corporation, 2:17-cv-00528
Amanda Sutliff v. Boston Scientific Corporation, 2:17-cv-00536
Tammy Tigner v. Boston Scientific Corporation, 2:17-cv-01241
Donna Wallis v. Boston Scientific Corporation, 2:17-cv-01312
Mary Helen Walseth v. Boston Scientific Corporation, 2:17-cv-01938
Gwendolyn Wilson v. Boston Scientific Corporation, 2:17-cv-02106
Susan Faso v. Boston Scientific Corporation, 2:17-cv-01862
Teresa Connors v. Boston Scientific Corporation, 2:17-cv-01134

Wendei Smith v. . Boston Scientific Corporation, 2:17-cv-01138
Zena Hardwick v. Boston Scientific Corporation, 17-CV-01977
Jennifer Atwood v. Boston Scientific Corporation, 2:17-cv-02202
Deann Lopez v. Boston Scientific Corporation, 2:17-cv-01155
Marsha Sue Jeter v. Boston Scientific Corporation, 2:17-cv-02508
Beverly Pamensky-Murray v. Boston Scientific Corporation, 2:17-cv-02093
Jennifer Atwood v. Boston Scientific Corporation, 2:17-cv-02202
Angela Benson v. Boston Scientific Corporation, 2:17-cv-01996
Louise Buttke v. Boston Scientific Corporation, 2:17-cv-02638
Glenda Dunford et al v. Boston Scientific Corporation, 2:17-cv-01979
Shelia Long v. Boston Scientific Corporation, 2:17-cv-00047
Anita Lynne Hauff et al v. Boston Scientific Corporation, 2:17-cv-01900
Arlyne Skalniak et al v. Boston Scientific Corporation, 2:17-cv-01925
Lisa Cutlip v. Boston Scientific Corporation, 2:17-cv-02505
Yvonne Spencer v. Boston Scientific Corporation, 2:17-cv-02553
Teresa Grigg v. Boston Scientific Corporation, 2:17-cv-00294
Mary Zeiter v. Boston Scientific Corporation, 2:17-cv-01098
Ida Adams v. Boston Scientific Corporation, 2:17-cv-02588
Dominique Allex v. Boston Scientific Corporation, 2:17-cv-02443
Cheryl Barnett v. Boston Scientific Corporation, 2:17-cv-02589
Roberta Black v. Boston Scientific Corporation, 2:17-cv-02730
Laceta Blalock v. Boston Scientific Corporation, 2:17-cv-02446
Claire Casale v. Boston Scientific Corporation, 2:17-cv-02447
Carolyn Childress v. Boston Scientific Corporation, 2:17-cv-02590
June Clark v. Boston Scientific Corporation, 2:17-cv-02448
Bonnie Cole v. Boston Scientific Corporation, 2:17-cv-02449
Edwina Daniell v. Boston Scientific Corporation, 2:17-cv-02486
Penny Dickeson v. Boston Scientific Corporation 2:17-cv-02592
Debra Gottfreid v. Boston Scientific Corporation, 2:17-cv-02646
Linda Henjum v. Boston Scientific Corporation, 2:17-cv-02734
Sandra Mallory v. Boston Scientific Corporation, 2:17-cv-02459
Delores Martin v. Boston Scientific Corporation, 2:17-cv-02738
Joyce Martin v. Boston Scientific Corporation, 2:17-cv-02461
Dolores Martinez v. Boston Scientific Corporation , 2:17-cv-02739
Marlene McFolling v. Boston Scientific Corporation, 2:17-cv-02596
Belinda McSween v. Boston Scientific Corporation, 2:17-cv-02462
Mary Melrose v. Boston Scientific Corporation, 2:17-cv-02467
Geraldine Morales v. Boston Scientific Corporation, 2:17-cv-02742
Flora Morgan v. Boston Scientific Corporation, 2:17-cv-02597
Annie Porter v. Boston Scientific Corporation, 2:17-cv-02470
Angel Pouncy v. Boston Scientific Corporation, 2:17-cv-02477
Nancy Reid v. Boston Scientific Corporation, 2:17-cv-02598
Lori Reyes v. Boston Scientific Corporation, 2:17-cv-02599
Ellen Rinaldi v. Boston Scientific Corporation, 2:17-cv-02600
Andra Shaw v. Boston Scientific Corporation, 2:17-cv-02745
Anne M. Shepard v. Boston Scientific Corporation, 2:17-cv-02481

Judy Smith v. Boston Scientific Corporation, 2:17-cv-02483
Margaret Wallace v. Boston Scientific Corporation, 2:17-cv-02450
Melody Woodard v. Boston Scientific Corporation, 2:17-cv-02601

**PLAINTIFFS' MOTION AND MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF STEPHEN
F. BADYLAK, D.V.M., Ph.D., M.D.**

Pursuant to Federal Rules of Evidence 702, 403 and 104, Plaintiffs submit this Motion and Memorandum of Law in Support of their Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., PhD., M.D.

Introduction and Summary

Dr. Badylak is a medical doctor and biomaterials scientist who has experience in the field of biomaterials as they relate to tissue engineering and regenerative medicine and the design of implantable surgical mesh devices, including polypropylene. Dr. Badylak has previously been precluded by this Court from offering testimony related to the MSDS's medical application caution. *Tyree v. Boston Sc. Corp.*, No. 2:12-cv-08633, 2014 U.S. Dist. LEXIS 155138 at *47 (S.D. W. Va., Oct 29, 2014). Unfortunately, Dr. Badylak again attempts to opine on this subject as well as several others that are outside his expertise and are unreliable and unsupported. Specifically, Dr. Badylak attempts to offer inappropriate opinions related to the risks and benefits of the various mesh products manufactured by Defendant Boston Scientific, opinions on the clinical implications of his microscopic findings and opinions related to oxidative degradation of polypropylene mesh within the more than thirty (30) women he examined pathological samples from. Because each of these opinions lacks the required reliability of Rule 702, these opinions should be excluded by the Court.

Arguments and Authorities

The proponent of expert testimony must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) is “based upon sufficient facts or data,” (3) is “the product of reliable principles and methods” and (4) has been reliably applied “to the facts of the case.” Fed.R.Evid. 702. Opinion evidence may be admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993).

Even if the expert is qualified and the testimony is reliable, “testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, the testimony must “fit” the case, *i.e.* there must be a “valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

A. Dr. Badylak’s State of Mind or Intent Opinions Related To Material Safety Data Sheets (MSDS) Should Be Struck.

This Court previously excluded the exact same testimony of Dr. Badylak that Boston Scientific now seeks to offer into evidence. *Tyree v. Boston Sci. Corp.*, 2014 U.S. Dist. LEXIS 155138 at *47. Dr. Badylak offers unreliable and unhelpful opinions related to material safety data sheets (MSDS) created by Chevron Phillips for the type of polypropylene used by Boston Scientific in its manufacturing of transvaginal mesh.¹ These MSDS opinions are a backdoor attempt by Dr. Badylak to offer opinions about Chevron Phillips’ state of mind or intent which

¹ Additionally, Dr. Badylak has offered no evidence in his reports, deposition, or resume that he has any experience creating, reviewing, or analyzing MSDS. Therefore, he is likewise unqualified to offer opinions related to MSDS.

has routinely been excluded by this Court. *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*. 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013). These same opinions should be excluded here.

At issue are the MSDS created by Chevron Phillips, the manufacturer of the Marlex polypropylene used in Boston Scientific mesh products, including the Obtryx product. Chevron Phillips added the following statement in the Marlex MSDS:

MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

Exhibit 1 at pg. 1. Lacking any personal knowledge or identifying any review of relevant documents, Dr. Badylak opines “[t]here was a change in the language of the MSDS in the 2004 timeframe, this language was not associated with any change in the characteristics of the raw material. I have not seen any evidence to indicate the additional language was supported by safety concerns or other scientific data.” Exhibit 2 at pg. 6 (Expert Report of Stephen F. Badylak, D.V.M., Ph.D., M.D.); Exhibit 3 at pg 1 (Supplemental)². Dr. Badylak further offers the conclusion that Chevron Phillips “was not based upon, nor supported by, safety concerns, scientific testing or data” Exhibit 3 at pg.1 (supplemental report). Dr. Badylak’s new basis for this opinion is his own version of a deposition of a Chevron Phillips employee, Mr. Frank Zakrzewski. Dr. Badylak’s supplemental report restates his version of testimony rather than quoting from the transcript citations:

² Due to the method of expert disclosure in these cases, it is unclear whether Dr. Badylak will be utilizing his supplemental report. Regardless, it is clear he intends on offering these opinions on the MSDS.

- The medical application caution *was not* added based on scientific testing that was conducted (45:24-46:5, 64:22-65:4) – and that the statement is not unique to polypropylene MSDSs. (54:19-55:1).
- The medical application caution was not added based on any specific scientific data on polypropylene (46:6-11); any scientific basis (184:11-14); review of any scientific or medical literature (47:8-15); or scientific concerns with vaginal mesh (47:16-21)...
- Mr. Zakzewski unequivocally testified that the medical application statement added in 2004 to the MSDS for Marlex HGX-030-01 was not added because of any scientific testing performed, any specific scientific data on polypropylene, review of the scientific or medical literature for polypropylene, or because of any science based concern (generally or specific to vaginal mesh).

Exhibit 3 at pgs. 2-3. While this entire effort is an inappropriate attempt by Dr. Badylak to testify as to Chevron Phillips' state of mind, the most fatal flaw in this effort is exposed when one looks at the actual testimony. When one looks at Mr. Zakzewski's actual deposition, it does not say what Dr. Badylak claims it says. Instead, Mr. Zakzewski specifically and repeatedly testified that he is "not aware" and does not know one way or the other if there was a scientific basis for the addition of the Medical Application Caution and that any opinion he could offer would be pure "speculation." Plaintiff apologizes for the length of the following deposition quotes but they are necessary for the Court to see the methodological flaws and inaccuracies in Mr. Badylak's opinions:

Deposition of Frank Zakzewski

Q. There's no scientific basis for the statement in the MSDS?

A. **That would be speculation. I don't know.**

Q. You're not aware of any - -

A. **I'm not aware of any.**

Q. - - scientific basis to support the MSDS - -

Q. - - medical caution statement?

A. Yeah, I wasn't involved in the change or what was added.

Exhibit 4 at 183:16-184:8 (Deposition of Frank Zakrzewski);

Q. Do you know who wrote the MSDS?

A. I do not.

Q. Was the medical application statement that we've highlighted in Deposition

Exhibit 3 added to the polypropylene MSDS based on any scientific testing that was conducted?

A. Not that I'm aware of, no.

Q. And was the medical application statement for polypropylene in the MSDS marked as Deposition Exhibit 3 added based on any specific scientific data on polypropylene?

A. No. Not that I'm aware of.

Id. At 45:22-46:11;

Q. Was the medical application statement that we're looking at in Deposition Exhibit 3 added to the polypropylene MSDS based on any review of the scientific or medical literature on polypropylene?

A. Yeah, I'm not aware of any testing or information on polypropylene related to this statement.

Id. At 47:8-47:15;

Q. The fact that you do not know whether there is any specific testing does not mean that those statements don't have a scientific basis?

A. I don't know the reasons that the statements were put on there.

Id. At 140:16-23 (emphasis added). In fact, Mr. Zakrzewski explicitly removed any evidentiary basis for Dr. Badylak's original speculative opinion that the MSDS language was added for liability lawsuits:

Q. Okay. Was the medical application statement added to the material safety data sheet for Marlex polypropylene in January of 2004 for legal reasons?

- A. **I would say that legal had some input into the MSDS, but I don't know that for certain because I didn't write it.**

Id. at 45:13-20.

Dr. Badylak cannot re-craft testimony and speculate as to a third party's state of mind in a desperate effort to justify his previous speculation that Chevron Phillips had no basis for the addition of the Medical Caution Application in the MSDS. Dr. Badylak is burdened by the fact that this is not what Mr. Zakrzewski did "not know one way or another" why Chevron Phillips included the Medical Caution Application in MSDS. There is no evidence to support any of Dr. Badylak's speculations related to Chevron Phillips' reasoning for the MSDS language and his opinions are inherently flawed.

Dr. Badylak's opinions about the MSDS are actually a backdoor attempt to testify as to Chevron Phillips' state of mind or intent. Absent the misquoted testimony of Mr. Zakrzewski, Dr. Badylak has no evidence as to why Chevron Phillips included the Medical Application Caution in the MSDS, but somehow he opines that whatever the reason, it had no basis. This opinion is an attempt to opine on Chevron Phillips' state of mind. This Court has consistently held that such state of mind opinion - - even when supported by evidence - - "is not a proper subject for expert or even lay testimony." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*. 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013). For these reasons. Dr. Badylak's opinions related to MSDS should be excluded.

- B. **Dr. Badylak cannot proffer any opinions relating to the risk/benefit analysis or safety and efficacy of the devices.**

Any opinions from Dr. Badylak relating to a risk/benefit analysis for the use of polypropylene mesh devices, or their overall safety and efficacy, must be excluded because he has neither reviewed the applicable scientific and medical literature, nor has he used these devices – or treated patients with these devices – in his practice.

1. Dr. Badylak cannot proffer *general* opinions relating to the risk/benefit or safety and efficacy of the devices.

Any opinions relating to a risk/benefit determination, or the overall safety and efficacy of the devices, in general, would be unqualified and unreliable coming from Dr. Badylak. First, Dr. Badylak cannot base these opinions on his review of the applicable medical literature because he admitted that he conducted no such review. Likewise, he cannot base such opinions on his own clinical experience relating to the use of these devices in patient – or treating the resulting complications – because he has never implanted, explanted, or treated patients with complications due to the devices.

As Dr. Badylak testified during his recent deposition, he has not conducted a comprehensive review of the literature relating to the devices for which he seeks to provide an opinion:

Q: So specific – I want to ask specific to the Obtryx device. Have you done a comprehensive review of the literature relating to the safety and efficacy specific to the Obtryx device?

A: **Comprehensive review, no.**

Q: Okay. Specific to the lynx device, have you done a comprehensive literature review to the safety and efficacy of that device?

A: **No, and the answer would be same for any of that I have not done what you're referring to as a comprehensive review of...devices specifically.**

Ex. 5 at 111:1-15. Similarly, Dr. Badylak did not perform an adequate literature search and review relating to the deformation of mesh *in vivo*. *Id.* at 78:8-12; 81:5-82:11.

As this Court has held: “[a]n expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead “selectively [chooses] his support from the scientific landscape.” *Tyree v. Boston Sci. Corp.*, 2014 U.S. Dist. LEXIS 155138, *19 (quoting *IN re Rezulin Products Liab. Litig.*, 369, 425 (S.D.N.Y. 2005)). Contrary to what is required of him as an expert, Dr. Badylak has simply chosen not to review the literature relevant to the opinions that he seeks to proffer. *Id.*; see also *Rimbert v. Eli Lilly & Co.*, CIV 06-0874 JCH/LFG, 2009 U.S. Dist. LEXIS 68851, 2009 WL 2208570, at *14 n. 19 (D.N.M. July 21, 2009) *aff’d*, 647 F.3e 1247 (10th Cir. 2011)(excluding expert for ignoring studies – finding her methodology to be reliable.). For that reason, Dr. Badylak’s opinions regarding the safety and efficacy – or the risk/benefit – of these devices should be excluded.

Additionally, Dr. Badylak’s opinions find no support from his own clinical practice. Indeed, he admitted during his deposition that he has no experience using or treating women with these devices. More specifically, as Dr. Badylak testified:

Q. Okay. Now, Doctor, you’re not a practicing clinical pathologist, is that correct?

A. **That’s correct?**

Q. You’re not a gynecologist, correct?

A. **Correct.**

Q. Not a urologist, correct?

A. **Correct.**

Q. You’re not a Euro gynecologist [*sic*], correct?

A. **Correct.**

Q. You’re not a practicing surgeon, is that correct?

A. **That’s correct.**

Ex. 5 at 33:17-34:3. Simply put, Dr. Badylak has no clinical experience in which he would ever need to consider the safety and efficacy of these devices or apply a risk/benefit analysis when treating a woman with stress urinary incontinence or pelvic organ prolapse. Because Dr. Badylak's opinions are based upon neither a comprehensive review and understanding of the relevant literature nor his own clinical experience, they lack reliability and should be excluded.

2. Dr. Badylak cannot proffer *case-specific* opinions regarding the risk/benefits or safety and efficacy of the devices.

Like with his general opinions, any case-specific opinions relating to risk/benefits and safety and efficacy of the devices would lack scientific reliability. Dr. Badylak admits that he did not review any of the plaintiffs' medical records. Ex 5 at 36:25-37:8, 41:6-11. Likewise, he admitted that he could not testify as to whether any of the individual plaintiffs had complications due to their mesh. *Id.* at 44:1-5. In fact, Dr. Badylak himself has testified that he is not able – and was not asked – to provide an opinion relating to the risk/benefit analysis for the use of the device implanted in any particular plaintiff. *Id.* at 108:11-2.

Therefore, Dr. Badylak has no basis to provide testimony on the risks and benefits related to these Boston Scientific devices.

C. Dr. Badylak should be precluded from offering *any* opinions relating to the correlation (or lack of correlation) of microscopic findings with clinical symptoms.

Dr. Badylak should be precluded from offering any opinions relating to the ability or inability of a pathologist to correlate any of the microscopic findings in this case with physical symptoms. First, and foremost, Defendant Boston Scientific never disclosed Dr. Badylak for this purpose. Despite never being disclosed for these opinions, Dr. Badylak testified in his deposition that:

- It's not possible to ascribe pain with any degree of certainty based upon the morphology of the tissue response to the device like surgical mesh product. Ex. 5 at 46:13-22
- I don't see how you could possibly ascribe dyspareunia to the typical changes that occur in a pathologic exam of a tissue specimen. *Id.* at 48:18-21.

When forming these opinions, Dr. Badylak was aware of scientific and medical literature correlating microscopic findings with physical symptomatology, but inexplicably never cited or relied upon any of this body of literature in forming his opinions. Ex 5 at 68:22-69:3, 67:13-67:17. Dr. Badylak recognized that scar tissue and innervation have been well studied as a source of pain in burn victims. *Id.* at 61:20-62:16. According to Dr. Badylak, "when you get to the part, though, of subjective symptoms, typically that's what we call an association. You can say, okay, if these changes are there and they're associated, but we avoid cause effect type conclusion." *Id.* at 62:10-16. According to Dr. Badylak, "If you do a strong enough study and you get strong enough associations, you start to think that causations there." *Id.* at 67:24-69:3.

Despite the large body of science detailing correlating morphological features with symptoms, Dr. Badylak never provided support for his opinions that it is not possible to associate the mechanisms of pain with morphological changes in tissue. Dr. Badylak never studied the source of pain or dyspareunia from mesh in a research setting. *Id.* at 64:2-12. As this Court has previously recognized:

An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable."

Tyree v. Boston Sci. Corp. 2014 U.S. Dis. LEXIS 155138 at *0. Thus, because Dr. Badylak never supported his opinions or considered the voluminous science to the contrary, his opinions should be considered unreliable under *Daubert*.

D. Dr. Badylak should be precluded from offering *any* opinions related to oxidative degradation.

Dr. Badylak should be precluded from offering any opinions related to degradation in these cases. In his expert report, Dr. Badylak states that “Type-1 polypropylene mesh is non-toxic, non-carcinogenic and non-degradable in the body.” Report of Stephen F. Badylak, DVM, MD, PhD, dated Nov. 21, 2014 attached at Ex. 2 at 15. Dr. Badylak supports his opinions with his physical observations of tissue samples from the Plaintiffs in these cases and his review of the peer reviewed scientific literature. However, Dr. Badylak’s opinions are nothing more than the result of willful blindness as revealed by the testimony he offered at deposition.

First, Dr. Badylak cannot support his opinions on the clinical impact of degradation because he failed to investigate the evidence in support of the degradation that was readily available to him and instead relied upon untested alternative hypotheses. While Dr. Badylak stated that he doesn’t “agree that his [Dr. Iakovlev’s] interpretation of what he’s looking at exists, I would have no idea how to evaluate that.” Ex. 5 at 96:20-24. Dr. Badylak had the full opportunity to investigate and evaluate Dr. Iakovlev’s findings himself. Dr. Badylak had Dr. Iakovlev’s full report and methodology prior to writing his own report. *Id.* at 97:5-97:17. Dr. Badylak had photographs and illustrations of Dr. Iakovlev’s findings. *Id.* Dr. Badylak even confirmed that he had access to the same types of tools utilized by Dr. Iakovlev in his report. *Id.* at 101:23-102:7. Yet, alarmingly, Dr. Badylak never looked for the layer observed and described by Dr. Iakovlev. At deposition, Dr. Badylak was asked:

Q: I’m asking if you saw visually what he reports as degradation bark?

A: No, but (sic) that's with scanning electron microscope or a - - he also used a birefringent method to try to evaluate this. I do not use those methods in my evaluation.

Id. at 92:19-24. Perhaps even more concerning is the fact that Dr. Badylak did not even explore ways to confirm or disprove the Iakovlev findings. Ex. 5 at 103:24-104:4. When asked, Dr. Badylak simply stated, "I could have done those if I thought they would have yielded any information." *Id.* at 97:20-21. However, the record reveals that Dr. Badylak further failed to do any scanning electron microscopy ("SEM") or myeloperoxidase staining to investigate the source of the degradation layer. *Id.* at 104:24-105:4. While Dr. Badylak failed to do any testing and could not identify the layer described by Iakovlev, he steadfastly held to his opinions that there was no clinical impact to oxidative degradation. *Id.* at 121:6-122:15.

Simply put, Dr. Badylak did not find evidence of degradation because he did not look for it. Dr. Badylak should be precluded under Rule 702 from offering testimony related to clinical findings or the clinical implication of degradation because of his willful blindness towards it. "Testing, in particular, is often a key component of the *Daubert* inquiry, and the failure to properly test a hypothesis is often grounds for excluding expert testimony in this jurisdiction. *See, e.g., Marsh v. W.R. Grace & *555 Co.*, 80 Fed.Appx. 882 (4th Cir. 2003); *Tunnell v. Ford Motor*, 245 Fed.Appx, 283, 287 (4th Cir. 2007). Also, of critical importance to the *Daubert* inquiry is that the expert rule out alternative hypotheses. *See Higginbotham v. KCS Intern.*, 85 Fed.Appx, 911, 916 (2004)." *Fireman's Fund Ins. Co., v. Tecumseh Products Co.*, 767 F. Supp. 2d 549, 554-55 (D. Md. 2011). In this case, Dr. Badylak not only failed to test, but failed to consider the results of Dr. Iakovlev's work as an alternative.

Secondly, Dr. Badylak's report describes his opinion that the concept of degradation is unsupported by the scientific community, yet Dr. Badylak contradicts himself at this deposition by stating:

I'm aware of the literature and the discussion, I'm aware of phenomenon of oxidative changes and oxidative reactions in the body everywhere, including the surface of biomaterials so, yes, I've considered it.

Ex. 5 at 122:2-6. Moreover, when asked if he could rule out degradation as occurring in any of the women in these cases, he stated that he could not. According to Dr. Badylak, "I am on record as saying oxidative reactions occur everywhere, including the surface of biomaterials." *Id.* at 122:9-11. Thus, Dr. Badylak's testimony does not support the opinions in his Rule 26 report. Dr. Badylak readily concedes that degradation does occur and that he cannot rule it out in these women.

Thus, because Dr. Badylak failed to test for degradation and its byproducts in the women he reviewed and failed to exclude the possibility of degradation, he should be precluded from testifying that degradation does not occur or does not contribute to clinical symptoms.

CONCLUSION

For the foregoing reasons, Dr. Badylak's proposed testimony and opinions outlined above are inadmissible and should be excluded.



DATED: January 11, 2018

Brian A. Goldstein, Esq.
brian.goldstein@cellinoandbarnes.com
CELLINO & BARNES, P.C.
2500 Main Place Tower
350 Main Street
Buffalo, New York 14202-3725
Telephone: (800) 888-8888

CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2018, a true and correct copy of this Response and exhibits was served via electronic mail with the Clerk of the Court using the CM/ECF System, which will send notification of such filing to the CM/ECF counsel of record.



Brian A. Goldstein, Esq.